

Column 4, sixth paragraph:

With particular reference to FIG. 8, tank 96 includes an air vent and overflow tube 110, and a float switch 112. The float switch is in turn connected to a control circuit 114 to permit operation of the device only when sufficient fluid is present. Heater 94 comprises a tubular channel having an electric heating rod 116 therein, and the heating rod is connected to a temperature control circuit 118 which is in turn also connected to control circuit 114. As fluid flows from tank 96 through filter 98 and through heater 94, it is warmed, and the temperature is measured by temperature probe 120, which is located in the outlet of heat 94. Temperature control probe 120 is connected to temperature control circuit 118 to control energization of heating road 116. A second temperature control probe 122 is also located in the outlet of heater 94 and is connected to control circuit 114 to ensure that the temperature does not exceed a predetermined level. If the temperature of the warming fluid is too high, the blood cells could be destroyed, and it is thus important either to automatically shut down the heating system or to activate an alarm such as that shown at 124.

#### **Remarks**

The following is a response to the Office Action dated February 28, 2003.

In response to item 1 of the Office Action in which it was noted that the Reissue oath/declaration was defective, applicant respectfully submits that the examiner may have overlooked the Supplemental Declaration that was filed on July 5, 2003 in response to the Notice to File Missing Parts. In the Declaration, signed by the inventor, pursuant to 37 CFR 1.175(a)(1), the inventor states that the original patent was inoperative or invalid by reason of the patentee claiming more or less than the patentee had a right to claim in the patent. Given that a Supplemental Declaration has been submitted and that there is no error in this Supplemental Declaration, applicant respectfully submits that item 1 of the Office Action is moot. Accordingly, the rejection

of claims 1-21 as being based on a defective reissue declaration under 35 U.S.C. 251, per stated in item 2 of the Office Action, is believed to have been overcome.

Per the above Amendment, the disclosure has been corrected to amend the reference numeral "\$2" to "52". In addition, another minor typographical error has been corrected.

Claims 15 and 17 were rejected under 35 U.S.C. 102(b) as being anticipated by EPO patent application No. EP 0180525 A1 (Thermodynamics). Moreover, claims 16 and 18 were rejected under 35 U.S.C. 103(a) as being unpatentable over Thyermodynamics in view of Egeler Offenlegungsschrift DE 3443085 A1.

Per the Preliminary Amendment filed on July 5, 2002, along with the other documents filed in response to the Notice to File Missing Parts, claim 15 was amended to specifically recite that there is "a helical passageway for said physiological fluid between said central and outer tubes" whereby the physiological fluid passes. Such "helical path" is supported by the disclosure of the instant application on column 3, lines 23-25 of the issued '749 patent from which the instant reissue application is based. By having a helical passageway, the physiological fluid is passed smoothly from one end of the heat exchanger to the other end, while being heated by the surface of the continuously helical groove formed on the exterior of the central tube.

In contrast, the Thermodynamics reference discloses an inner tube 10 formed with a series of annular corrugations 12 that is covered by an outer tube 20. As best shown in Figs. 1 and 2, the ridges 14 of inner tube 10 have a diameter that is less than the diameter of passage 21. (Page 9, lines 15-17) In other words, there is no contact between ridges 14 of inner tube 10 and the inner surface of outer tube 30. As a consequence, the fluid that passes between the space separated by inner tube 10 and outer tube 20 is met by the series of corrugations 12 so that turbulence is created for the passing fluid. In the case of flowing blood, such turbulence tends to have an

adverse effect. Indeed, this is acknowledged by Thermodynamics in the embodiment shown in Figs. 4 and 5. For the Fig. 4 embodiment, the inner tube 410, which is in corrugated form, is helically wound about a center body 440 so as to restrict the flow of blood in a direction parallel to the annular corrugation across the various coils from inlet port 432 to outlet port 434. (Page 11, line 13 to page 12, line 7) The cross-sectional view of Fig. 5 clearly shows a number of openings 430 that are aligned in parallel to guide the passage of blood.

The heat exchanger of the instant invention, on the other hand, has a helical path through which the physiological fluid to be infused to the patient passes. As a consequence, there is a smooth continuous flow of the being temperature regulated fluid from the inlet port to the outlet port.

In view of the foregoing, applicants respectfully submit that claims 15 and 17 each are not anticipated by Thermodynamics.

As for the reliance of the Egeler '085 publication by the examiner for rejecting claims 16 and 18, applicant is unable to comment on Egeler or traverse the examiner reliance of Egeler, insofar as Egeler is written in German and therefore is incomprehensible to applicant. However, applicant reserves the right to traverse the rejection of Egeler with Thermodynamics and also would like to point out that insofar as each of claims 16 and 18 depends from claim 15 and claim 15 is believed to be patentable over the prior art, claims 16 and 18 are likewise believed to be patentable over the prior art.

In view of the foregoing, the examiner is respectfully requested to reconsider the application and pass the case to issue.

Respectfully submitted,



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**VERSION TO SHOW MARKINGS TO SHOW CHANGES MADE** TECHNOLOGY CENTER R3700

**Attachment Specification Portions Pursuant to 37 C.F.R. 1.121(b)(1)(iii)**

Please amend the specification as follows:

Column 4, first paragraph:

B<sup>1</sup> It will be appreciated that heat exchanger 10 may be easily attached to pole 4 by inserting end 54 into fluid connector 38 and by lowering fluid connector 36 onto end [52]. When this is accomplished, heat exchanger 10 will be supported mainly by fluid connectors 36 and 38.

Column 4, sixth paragraph:

B<sup>2</sup> With particular reference to FIG. 8, tank 96 includes an air vent and overflow tube 110, and a float switch 112. The float switch is in turn connected to a control circuit 114 to permit operation of the device only when sufficient fluid is present. Heater 94 comprises a tubular channel having an electric heating rod 116 therein, and the heating rod is connected to a temperature control circuit 118 which is in turn also connected to control circuit 114. As fluid flows from tank 96 through filter 98 and through heater 94, it is warmed, and the temperature is measured by temperature probe 120, [ \_ ] which is located in the outlet of heat 94. Temperature control probe 120 is connected to temperature control circuit 118 to control energization of heating road 116. A second temperature control probe 122 is also located in the outlet of heater 94 and is connected to control circuit 114 to ensure that the temperature does not exceed a predetermined level. If the temperature of the warming fluid is too high, the blood cells could be destroyed, and it is thus important either to automatically shut down the heating system or to activate an alarm such as that shown at 124.